UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,516	02/07/2001	Wei-Yu Lo	12875-002001 / 0643-5299U	3185

26161 7590 12/15/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,516	LO ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12 and 14* is/are allowed.

6)☒ Claim(s) *13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 24 September 2004 in response to the Non-Final Office Action mailed 22 July 2004. Claims 1-16 were considered in the 22 July Office Action. Claims 2-6 were amended in the 24 September Paper. Claims 1-16 are pending and under consideration.

Response to Amendment

Specification

The disclosure stands objected to because of the following informalities: The specification contains sequence disclosures that are not identified by SEQ ID NO (*e.g.*, page 14, lines 24-25 and page 15, lines 16-17). In response, Applicant argues that the primers set forth in the specification are disclosed in the sequence listing. It would seem that Applicant has misunderstood the objection. "Where the description or claims of a patent application discuss a sequence that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by 'SEQ ID NO:' in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application" (37 CFR 1.821(d), emphasis added). Thus, sequences referred to in the specification must be referenced by SEQ ID NO, even if the sequence is embedded in the text.

Claim Objections

Objection to claims 2, 4, 5 and 6 is withdrawn in view of the amendments thereto.

Claim Rejections - 35 USC § 112

Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record and herein below in the "Response to Arguments".

Claims 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as comprising new matter for reasons of record and herein below in the response to arguments.

Rejection of claims 3 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendment thereto.

Response to Arguments

Claim Rejections - 35 USC § 112

Claim 13 is rejected as lacking enablement for a DNA vaccine composition comprising the broad scope of "an antigenic gene". In response to the *prima facie* case and arguments of record, Applicant alleges that the specification clearly teaches a number of uses of the claimed composition. Applicant particularly points out the teaching at page 2, lines 11-15 of the specification, which reads in full, "the object of the present invention is to construct a vector without antibiotic resistance gene and use harmless host cell to express heterologous genes in an organism or as a DNA vaccine or health food, thereby raising the safety and enhancing the immune responses" (emphasis added). Applicant misquotes this passage by deleting the thereby statement, which clearly indicates that purpose of expressing heterologous genes in an organism

or as a DNA vaccine or health food is to elicit an immune response, said immune response being enhanced by the claimed vector. Thus, to the extent that the composition is limited to being immunogenic, there is no asserted utility other than vaccination, which is not enabled by the disclosure. Therefore, Applicant's arguments, viewed in context of the record as a whole, are not persuasive and the claims stand rejected as lacking enablement.

Claims 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as comprising new matter. The claims were rejected because the originally filed specification and claims do not disclose a sequence for the Rep A protein and, therefore, the limitation of the claimed subject matter to comprising a specific "sequence of the Rep A protein" constitutes new matter.

In response Applicant argues that the specification at page 7, lines 21-28, teaches, a "Rep A protein...of 317 amino acids" and cites papers that disclose nucleic acids encoding the Rep A protein. Applicant points out that Bouia *et al.*, as well as the corresponding GenBank record, disclose a 317 amino acid Rep A protein and the encoding nucleotide sequence. Applicant further submits an exhibit showing that nucleotides 262-1215 of GenBank M31223 encodes the Rep A protein, which nucleotides are the same as nucleotides 3198-4151 of the instant SEQ ID NO: 1.

These arguments and exhibits have been fully considered but are not deemed persuasive. It is noted that the specification makes no explicit reference to the sequence delimited by nucleotides 3198-4151 of SEQ ID NO: 1 and nothing that would limit the Rep A protein referred to in the specification to being encoded by that sequence. Thus, the skilled artisan would not have identified the region cited by Applicant based on the disclosure alone. With regard to the

teachings from the art relied upon to support applicants arguments, MPEP 608.01(p) I. A. states, "[a]n application for a patent when filed may incorporate 'essential material' by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below. 'Essential material' is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode" As the sequence of the Rep A protein defines the subject matter of claims 15 and 16 it cannot be incorporated by reference from the non-patent literature. Still further, mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Thus, even if one could incorporate essential material from the nonpatent literature by reference, such incorporation by reference must be explicitly made. Thus, the mere reference to art that discloses a Rep A protein sequence does not support claims directed to that sequence, or a nucleic acid encoding that sequence.

Applicant's arguments in view of the record as a whole are not deemed persuasive. Therefore, the claims stand rejected under 35 USC §112, first paragraph, as lacking descriptive support in the originally filed application.

New Grounds

Specification

The amendment filed 24 September is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added sequences set forth as SEQ ID NO: 7 and 8 and the definition of Rep A protein as being encoded by or comprising these sequences in the amended paragraph on page 7 of the specification constitute new matter. For the reasons set forth in the previous Office Action and herein above, the originally filed specification does not contain descriptive support for a polypetide comprising SEQ ID NO: 8 or a nucleic acid defined by the nucleic acid sequence set forth in SEQ ID NO: 7. Although SEQ ID NO: 1 comprises the sequence set forth as SEQ ID NO: 7, there is no disclosure of SEQ ID NO: 7 by reference to the particular region of SEQ ID NO: 1 comprising SEQ ID NO: 7 and there is no contemplation of SEQ ID NO: 7 independent of SEQ ID NO: 1. Therefore, the disclosure of a fragment of SEQ ID NO: 1 as SEQ ID NO: 7 and the protein encoded thereby constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

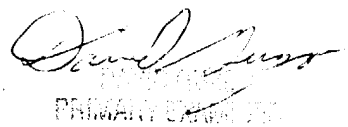
Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636